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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/687,483 | 10/13/2000 | Andreas Braun | 24736-2033 | 7859 |
| 47328 | 7590 | 02/27/2006 | EXAMINER | |
| BIOTECHNOLOGY LAW GROUP C/O PORTFOLIOIP PO BOX 52050 MINNEAPOLIS, MN 55402 | | | CLOW, LORI A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/687,483 | BRAUN, ANDREAS | |
| | Examiner | Art Unit | |
| | Lori A. Clow, Ph.D. | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 November 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4,5,9-15,31-34,43,44,47-50,54 and 98-128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,5,9-15,31-34,43,44,47-50,54 and 98-128 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/6/05.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicants' response, filed 18 November 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 4, 5, 9-15, 31-34, 43, 44, 47-50, 54, and 98-128 are currently pending. Claims 1-3, 6-8, 16-30, 35-42, 45, 46, 51-53, and 55-97 have been cancelled.

It is noted that the submitted claim listing states that claims 6-9 are cancelled. Applicant is requested to correct this in the next communication.

Information Disclosure Statement

The Information Disclosure Statement filed 6 October 2005 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 9-15, 31, 43, 44, 47-50, and 109-128 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 98/35609), in further view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209), for the reasons set forth in the previous Office Action.

Response to Applicants Arguments with regard to the above rejection

Applicant argues that “the Campbell reference does not teach selecting data from only individuals that have not been pre-selected for any particular disease” and that Campbell does not provide any motivation to be combined with Clausen.

This is not persuasive. As stated in the previous Office Action, Campbell is not relied upon to teach only individuals that have not been pre-selected for disease. Rather, Clausen et al. is relied upon for that embodiment. Clausen clearly teaches the benefit to studying only healthy members of a population (see previous Office Action at page 5).

Applicant further argues that “Campbell does not teach or suggest methods or systems related to a healthy database, that includes only healthy members of a population”. This is not persuasive, as stated above. Campbell is relied upon to teach the database in which information is deposited with data points relating to members of a population and associating the information with an indexer. Clausen is relied upon to teach that the study of only healthy members is beneficial, as was stated in the previous Office Action. The Examiner clearly set forth a motivation, contrary to Applicants statement that Campbell does not provided a motivation (see Office Action at page 5).

Applicant further argues that “Campbell does not obtain data from only individuals that are not selected on the basis of having a particular disease” and that there is “no motivation in Campbell to combine its teachings with any teaching taking data from just one pool of subjects. As the “just one pool of subjects” limitation is not a limitation of the instant claims, the point is moot. Further, the motivation has been stated by the Examiner in the Office Action, at page 5, as stated above.

Finally, Applicant argues that “Clausen does not teach or suggest the desirability of identifying new biomarkers by comparing two subpopulations, one healthy, and one manifesting some disease or other characteristic”.

This is not persuasive, as Clausen is relied upon to teach the “healthy population” limitation of the instant claims.

Claims 32-34, 98-100 and 102 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaugh et al.; Published 5 November 1994, PTO Form

1449, 20 February 2001, Reference BU), in view of Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209), in further view of US 5,498,545 (Vestal; published 12 March 1996; PTO Form 1449, 20 February 2001, Reference AI), for the reasons set forth in the previous Office Action.

Applicant's arguments with regard to this rejection refer back to the Campbell rejection above and have been addressed above.

Claims 54 and 101 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaugh et al.; Published 5 November 1994), in view of Campbell et al. (WO 98/35609), in further view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209), for the reasons set forth in the previous Office Action.

Applicant's arguments with regard to this rejection refer back to the Campbell rejection above and have been addressed above.

Claim 98 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209) in further view of US 5,498,545 (Vestal; published 12 March 1996), as set forth in the previous Office Action.

Applicant's arguments with regard to this rejection refer back to the Campbell rejection above and have been addressed above.

Claims 103-108 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0596205 A2 (Bullaugh et al.; Published 5 November 1994), in view of Campbell et al. (WO 98/35609), in view of Clausen et al. (Journal of Clinical Investigation (1996) Vol. 98, No. 5, pages 1195-1209), in view of US 5,498,545 (Vestal; published 12 March 1996) as applied to claims 100 and 102 above, in further view of US 6,602,662 B1 (Koster et al.; Published 5 August 2003; priority 18 March 1996; PTO 1449, 14 October 2003, Reference H), as stated in the previous Office Action.

Applicant's arguments with regard to this rejection refer back to the Campbell rejection above and have been addressed above.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1631

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 17, 2006
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

**MARJORIE A. MORAN
PRIMARY EXAMINER**

Marjorie A. - Moran
2/21/06